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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/586,142

12/13/2006

Akihiro Iida

50026/060001

1352

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7590

01/20/2012

CLARK & ELBING LLP
101 FEDERAL STREET
BOSTON, MA 02110

EXAMINER

BURKHART, MICHAEL D

ART UNIT

PAPER NUMBER

1633

NOTIFICATION DATE

DELIVERY MODE

01/20/2012

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

Office Action Summary	Application No. 10/586,142	Applicant(s) IIDA ET AL.	
	Examiner Michael Burkhart	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 3, 5-9 and 26-34 is/are pending in the application.
- 5a) Of the above claim(s) 6 and 29-34 is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 3, 5, 7-9, 26-28 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Receipt and entry of the amendment dated 10/31/2011 is acknowledged.

Election/Restrictions

Newly submitted claims 29-34 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: new claims 29-34 are placed into Group III as below.

Restriction is required under 35 U.S.C. 121 and 372.

Group III, claim(s) 29-34, drawn to kits comprising: 1) a CAG promoter operably linked to a bacteriophage RNA polymerase-encoding DNA; 2) DNAs encoding a minus-strand virus genome RNA operably linked to an RNA polymerase recognition sequence; 3) a CAG promoter operably linked to DNAs encoding minus strand RNA viral proteins that form a ribonucleoprotein with the genome RNA.

The groups of inventions listed above and in the Restriction Requirement dated 10/12/2010 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature linking Groups II and III are the DNAs found in Group III. However, such DNAs are not found to be a contribution over the prior art for reasons made of

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record (see the Office Action dated 6/1/2011) and reiterated below. To further complete the record, Ito et al (Micro. Immunol., 2003, of record) as evidenced by Neumann et al (J. Virol., 2005) teaches a plasmid (pC-T7pol) encoding the T7 RNA polymerase under control of the strong chicken β -actin promoter in the pCAGGS vector (page 10301, second column, second full ¶ of Neumann et al). The pCAGGS vector comprises the CAG promoter (instant specification and Niwa et al, 1991, cited by applicants).

Accordingly, Groups II and III are not so linked by the same concept or a corresponding technical feature as to form a single general inventive concept.

Since applicant has elected and received an action on the merits for Group II, claims 29-34 (Group III) are withdrawn from consideration as being directed to a non-elected invention.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 3, 5, 7-9, and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Inoue et al (J. Virol., 2003) in view of Waning et al (J. Virol., 2002), Ito et al (Micro. Immunol., 2003), Li et al (J. Virol, 2000), and Lerch et al (2003) as evidenced by Neumann et al

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(2005, J. Virol.). **This rejection is maintained for reasons made of record in the Office Action dated 6/1/2011, and for reasons set forth below.**

The claims have been amended to recite that the CAG promoter is used to directly express the RNA polymerase and the (-) strand viral RNP protein(s). Such limitations have already been addressed in the previous Office Action. Further, Ito et al teaches the plasmid pC-T7pol encoding the T7 RNA polymerase under control of the strong chicken β -actin promoter in the pCAGGS vector (page 10301, second column, second full ¶ of Neumann et al). The pCAGGS vector comprises the CAG promoter (instant specification and Niwa et al, 1991, cited by applicants).

Response to Arguments

Applicant's arguments filed 10/31/2011 have been fully considered but they are not persuasive. Applicants essentially assert that: 1) the cited art fails to teach the use of a cytomegalovirus enhancer and chicken b-actin promoter-comprising promoter as instantly recited; 2) the use of the CAG promoter in the instant invention produced unexpected results.

Regarding 1), this assertion is false on its face. The cited art utilizes the same "CAG" or "CA" promoter used by applicants in the instant specification, i.e. that which is found in the pCAGGS vector taught by Niwa et al (1991, cited by applicants). It is unexplained why the promoter found in the pCAGGS vector of the prior art is not to be considered anticipatory of the generically claimed " cytomegalovirus enhancer and chicken b-actin promoter-comprising promoter."

Regarding 2), the use of the CAG promoter is consistently found to yield higher expression than the use of the CMV promoter alone. See, for example, the results of Niwa et al

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(1991, of record). Thus, the expected benefits of using the CAG promoter in the rejection above would be two-fold: not only would more of the RNP proteins be available for virion assembly (they are expressed using the CAG promoter), but more of the viral genome would also be available because its production is controlled by the T7 polymerase, of which higher levels are expected because it is expressed via the CAG promoter. Applicants asserted “unexpected results” are therefore not so unexpected in light of the superiority of the CAG promoter versus the CMV promoter, particularly in certain cell lines. In light of the prior art teachings, what would be unexpected is if the CMV promoter performed better than the CAG promoter.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Burkhart whose telephone number is (571)272-2915. The examiner can normally be reached on M-F 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Burkhart/
Primary Examiner, Art Unit 1633